K073538 page 1 of 2.

MAR 12 2008

5. 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341

Contact: Tracy Maddock, RAC
Regulatory Affairs Analyst
Phone (610) 596-2240
Fax (610) 266-4962
E-mail: tracy.maddock@bbraun.com

DEVICE NAME: Dual Chamber TPN Container

COMMON OR USUAL NAME: TPN Bag

DEVICE CLASSIFICATION: I.V. Container
Class II, CFR Title 21 § 880.5025

PREDICATE DEVICE: B. Braun EVA TPN Container (K041415)
Churchill Medical Dual Chamber Empty Container (K041038)

DESCRIPTION: The Dual Chamber TPN (Total Parenteral Nutrition) Container is an empty, sterile pharmacy compounding container composed of ethylene vinyl acetate (EVA). The container is divided into two chambers separated by a flexible tube and rigid separator bar. Both chambers are designed to be filled via the tubing set attached to each chamber. The upper chamber is used for filling lipid emulsion. The lower chamber is used for filling other solutions such as dextrose, amino acids, and electrolytes. Additives may be introduced via the latex-free injection/medication port present on each chamber. Once both chambers are filled, the container is stored with the flexible tube and rigid separator bar in place until the time of administration to the patient.

At the time of patient use, the flexible tube and rigid separator bar are removed and the contents of the two chambers are combined. The contents are then administered to the patient using an intravascular administration set which is connected via the set port

located on the lower chamber. The Dual Chamber TPN Container will be offered in three sizes: 1500 mL, 3000 mL, and 4000 mL.

INTENDED USE:

The Dual Chamber TPN Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The Dual Chamber TPN Container can be filled either by gravity or in conjunction with automated compounding equipment.

SUBSTANTIAL EQUIVALENCE:

The B. Braun Medical Inc. Dual Chamber TPN Container has the same indications for use, similar materials of construction and similar manufacturing processes as the B. Braun EVA TPN Container, covered under K041415.

The B. Braun Medical Inc. Dual Chamber TPN Container has similar indications for use and is similar in design to the predicate device, the Churchill Medical Dual Chamber Empty Container, covered under K041038.

The Dual Chamber TPN Container was subjected to a variety of tests to demonstrate substantial equivalence with the two predicate devices and to demonstrate the safety and effectiveness of the proposed device. The following tests were conducted: biocompatibility, functional performance, package integrity, shipping, impermeability to microorganisms, and chemical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy Maddock
Regulatory Affairs Analyst
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

MAR 12 2008

Re: K073538
Trade/Device Name: Dual Chamber TPN Container
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: December 14, 2007
Received: December 17, 2007

Dear Ms. Maddock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

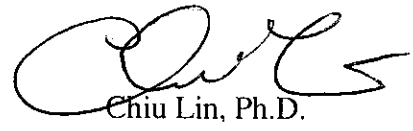
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073538

4. Indications for Use Statement

510(k) Number (if known): _____

Device Name: Dual Chamber TPN Container

Indications For Use:

The Dual Chamber TPN Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The Dual Chamber TPN Container can be filled either by gravity or in conjunction with automated compounding equipment.

Prescription Use ____X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. [illegible]
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073538